Potential for Contaminated Saline: DPH Recommends Stop Use of Nurse Assist Saline-Flush Syringes

DOVER – The Delaware Division of Public Health (DPH) is currently investigating an outbreak of *Burkholderia cepacia (B. cepacia)* bloodstream infections possibly associated with intravenous (IV) infusions. This outbreak is part of a multistate outbreak being investigated by the Centers for Disease Control and Prevention (CDC). The CDC has made DPH aware of the possibility of contaminated intravenous infusions of ***Nurse Assist pre-filled saline flushes*** shipped to local long term care facilities or other medical providers in Delaware.

DPH recommends that any health care facilities, providers, or anyone else who has received Nurse Assist prepackaged three-, five- and 10-millileter saline flush syringes immediately discontinue using and isolate these products until further notice. On Tuesday, October, 4, 2016, Haltom City, Texas-based Nurse Assist Inc., issued a voluntary recall of these products. The link to their press release can be found here: http://www.fda.gov/Safety/Recalls/ucm523959.htm. The lots being recalled were distributed to customers and distributors between 02/16/16 and 09/30/16. Nurse Assist is notifying its distributors and customers via email, phone call, and certified mail. Until an investigation can be completed, the company urges all health care facilities with affected product to discontinue use and return the product to the supplier.

Nurse Assist voluntarily recalled its I.V. Flush Syringes after becoming aware of patients that developed *Burkholderia cepacia* bloodstream infections while receiving intravenous

care using the company's prepackaged saline flushes.

B. cepacia, typically associated with respiratory infections in individuals with cystic fibrosis and other respiratory diseases, can also be transmitted from contaminated medications and devices. *B. cepacia* is frequently resistant to many common antibiotics. DPH is recommending consultation with infectious disease physicians in managing these patients.

"Bloodstream infections linked to *B. cepacia* can be quite serious. We are encouraging all medical providers to determine if they have used any of the potentially contaminated products and be vigilant in testing to identify such infections in patients who may have been exposed and are acutely ill," said DPH Director Dr. Karyl Rattay. "We are continuing to work closely with the CDC and other federal agencies as this situation evolves."

DPH was notified by infection control staff at a Delaware hospital that during the past month, three patients with blood cultures positive for *B. cepacia* had been admitted. All three are residents of the same long term care facility in Delaware and all are/were receiving long-term intravenous antibiotic therapy. All have since been discharged from the hospital and are back at the long term care facility.

DPH has reached out to medical providers, hospitals, and facilities known to have received the Nurse Assist products and is working with the Delaware Division of Long Term Care Residents Protection (DLTCRP) nursing homes.

"We are partnering closely with our long term care providers in Delaware to provide them the latest information," said Mary Peterson, director of the Division of Long Term Care Residents Protection. "We want providers to know that the contaminated saline flushes could pose a threat to their residents and that they should remove them from their shelves so that they are not used."

DPH issued a Health Alert Network (HAN) notification to medical providers statewide on October 3, 2016 about the investigation. DPH encourages health care providers to consider *B. cepacia* bloodstream infections in patients presenting with findings suggestive of sepsis, especially those with a history of IV infusion treatment through central venous lines and those who are (or have been) recent residents at long term care facilities.

While DPH is reaching out to the specific facilities that are believed to have received contaminated infusion solution, it also urges all medical providers to immediately report all non-respiratory cultures that are positive for B. cepacia since July 16, 2016, to DPH by phone at 888-295-5156 or by fax at 302-223-1540. The FDA encourages healthcare professionals and patients to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:
· Complete and submit the report Online: www.fda.gov/MedWatch/report
· Download form or call 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 800-FDA-0178

According to the CDC, the effects of *Burkholderia cepacia* on people vary widely, ranging from no symptoms at all to serious respiratory infections, especially in patients with cystic fibrosis. If you have received or are currently receiving intravenous infusions and are feeling unwell or have concerns about your health, contact your medical provider.

Several other states (Maryland, New York and Pennsylvania) have also identified possible links between the injection of this product and development of *B. cepacia* bloodstream infections. DPH continues to work with the CDC, the U.S. Food and Drug Administration (FDA), and other state health departments on the response to this outbreak.

A person who is deaf, hard-of-hearing, deaf-blind or speech-disabled can call the DPH phone number above by using TTY services. Dial 7-1-1 or 800-232-5460 to type your conversation to a relay operator, who reads your conversation to a hearing person at DPH. The relay operator types the hearing person's spoken words back to the TTY user. To learn more about TTY availability in Delaware, visit http://delawarerelay.com.

Delaware Health and Social Services is committed to improving the quality of the lives of Delaware's citizens by promoting health and well-being, fostering self-sufficiency, and protecting vulnerable populations. DPH, a division of DHSS, urges Delawareans to make healthier choices with the 5-2-1 Almost None campaign: eat 5 or more fruits and vegetables each day, have no more than 2 hours of recreational screen time each day (includes TV, computer, gaming), get 1 or more hours of physical activity each day, and drink almost no sugary beverages.